



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Nigel R.A. BEELEY *et al.*

Group Art Unit: 1646

Appln. No.: 10/629,649

Examiner: To Be Assigned

Filed: July 30, 2003

Atty. Docket: 18528.636

For: **Methods and Compositions for
Treating Polycystic Ovary Syndrome**

Confirmation No.: 6846

INFORMATION DISCLOSURE STATEMENT

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to the documents listed on the attached Form PTO-1449. Copies of the listed references were previously cited by or submitted to the Office in a prior application. Pursuant to 37 C.F.R. §1.97(d) and MPEP § 609, the prior application is identified by its U.S. Application Number in this Information Disclosure Statement on the attached Form PTO-1449, and the above-captioned application relies on the prior application for an earlier filing date under 35 U.S.C. § 120 of the listed documents are submitted herewith.

It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.



Nigel R.A. BEELEY *et al.*
Appln. No. 10/629,649
Page 2

CERTIFICATION AND/OR FEE

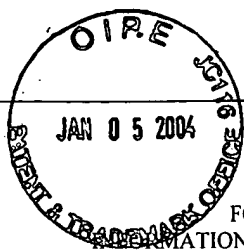
Because this Information Disclosure Statement is being submitted prior to issuance of the first action on the merits of the above-captioned application, no certification or fee is required.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408)
Milan M. Vinnola (Reg. No. 45,979)
Thomas E. Holsten (Reg. No. 46,098)

Date: January 5, 2004

ARNOLD & PORTER
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5000 telephone
(202) 942-5999 facsimile



FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

18528.636

APPLICATION NO.

10/629,649

APPLICANTS

Nigel R.A. BEELEY *et al.*

FILING DATE

July 30, 2003

GROUP

To Be Assigned

U.S. PATENT DOCUMENTS

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

Reference Provided

AA1

Ahles, "Toward a New Approach: Primary and Preventive Care of the Woman with Polycystic Ovarian Syndrome", Prim. Care Update Ob/Gyns., 7(6):275-278 (2000)

10/317,126

AB1

Balen, "Ovulation Induction for Polycystic Ovary Syndrome", Human Fertility, 3:106-111 (2000)

10/317,126

AC1

Barbieri, "Induction of Ovulation in Infertile Women with Hyperandrogenism and Insulin Resistance", Am. J. Obstet. Gynecol., 183(6):1412-1418 (2000)

10/317,126

AD1

Ciampelli and Lanzone, "Insulin and Polycystic Ovary Syndrome: a New Look at an Old Subject", Gynecol. Endocrinol., 12:277-292 (1998)

10/317,126

AE1

Conway, "Hyperinsulinaemia and Polycystic Ovary Syndrome", Human Fertility, 3:93-95 (2000)

10/317,126

AF1

Davison, "New Approaches to Insulin Resistance in Polycystic Ovarian Syndrome", Current Opinion in Obstetrics and Gynecology, 10:193-198 (1998)

10/317,126

AH1

Ehrmann, "Relation and Functional Ovarian Hyperandrogenism to Non-Insulin Dependent Diabetes Mellitus", Baillière's Clinical Obstetrics and Gynaecology, 11(2):335-347 (1997)

10/317,126

AI1

Franks, "Polycystic Ovary Syndrome", Medical Progress, 333(13):853-861 (1995)

10/317,126

AJ1

Franks *et al.*, "Insulin Action in the Normal and Polycystic Ovary", Endocrinology and Metabolism Clinics of North America, 28(2):361-378 (1999)

10/317,126

AK1

Hadine *et al.*, "Editorial: Polycystic Ovarian Syndrome - Relationship to Epilepsy and Antiepileptic Drug Therapy", J. Clin. Endocrinology & Metabolism, 86(7):2946-2949 (2001)

10/317,126

AL1

Hopkinson *et al.*, "Polycystic Ovarian Syndrome: the Metabolic Syndrome Comes to Gynaecology", BMJ, 317:329-332 (1998)

10/317,126

AM1

Iuorno *et al.*, "Insulin-Lowering Drugs in Polycystic Ovary Syndrome", Obstetrics and Gynecology Clinics of North America, 28(1):153-164 (2001)

10/317,126

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

18528.636

APPLICATION NO.

10/629,649

APPLICANTS

Nigel R.A. BEELEY *et al.*

FILING DATE

July 30, 2003

GROUP

To Be Assigned

U.S. PATENT DOCUMENTS

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

Reference Provided

AA2

Kim *et al.*, "Insulin Sensitizers and Polycystic Ovary Syndrome: Can a Diabetes Medication Treat Infertility?", Fertility and Sterility, 73(6):1097-1098 (2000)

10/317,126

AB2

Legro, "Polycystic Ovary Syndrome: Current and Future Treatment Paradigms", Am. J. Obstet. Gynecol., 179(6), part 2, pp. S101-S108 (1998)

10/317,126

AC2

Nestler, "Role of Hyperinsulinemia in the Pathogenesis of the Polycystic Ovary Syndrome, and Its Clinical Implications", Seminars in Reproductive Endocrinology, 15(2):111-122 (1997)

10/317,126

AD2

Olefsky and Saltiel, "PPAR γ and the Treatment of Insulin Resistance", TEM, 11(9):362-367 (2000)

10/317,126

AE2

Phipps, "Polycystic Ovary Syndrome and Ovulation Induction", Obstetrics and Gynecology Clinics of North America, 28(1):165-182 (2001)

10/317,126

AF2

Pugeat and Ducluzeau, "Insulin Resistance, Polycystic Ovary Syndrome and Metformin", Drugs, 58 Suppl. 1:41-46 (1999)

10/317,126

AH2

Rosenfield, "Current Concepts of Polycystic Ovary Syndrome", Baillière's Clinical Obstetrics and Gynaecology, 11(2):307-333 (1997)

10/317,126

AI2

Spiegelman, "PPAR γ in Monocytes: Less Pain, Any Gain?", Cell, 93:153-155 (1998)

10/317,126

AJ2

Udoff and Adashi, "Polycystic Ovarian Disease: A New Look at an Old Subject", Current Opinion in Obstetrics and Gynecology, 7:340-343 (1995)

10/317,126

AK2

Utiger, "Insulin and the Polycystic Ovary Syndrome", The New England Journal of Medicine, 335(9):657-658

10/317,126

AL2

Wolf, "Ovulation Induction", Clinical Obstetrics and Gynecology, 43(4):902-915 (2000)

10/317,126

AM2

Zacur, "Polycystic Ovary Syndrome, Hyperandrogenism, and Insulin Resistance", Obstetrics and Gynecology Clinics of North America, 28(1):21-33 (2001)

10/317,126

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.